

APPLICATION FOR
UNITED STATES LETTERS PATENT

SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

Be it known that I, Konstantin Valtchev, a citizen of Canada, and resident of the Province of Ontario, having a postal address of 233 Beecroft Road, Toronto, Ontario, Canada, M2N 6Z9, have invented a new and useful **"Urethral Sling Introducer and Method of Use"**, of which the following forms the specification.

"Urethral Sling Introducer and Method of Use"

BACKGROUND OF THE INVENTION

CROSS REFERENCE TO RELATED APPLICATIONS

Not applicable.

5 Field of the Invention

The present invention relates to the field of medical instruments employed to control female incontinence and in particular to an apparatus for installing a sub-urethral sling and the method of installing the urethral sling.

Description of Related Art

10 As can be seen by reference to the following U.S. Patent Nos. 6,478,727; 6,030,393; 5,899,909; 6,491,703; and 6,273,852, the prior art is replete with myriad and diverse surgical instruments employed for the sole purpose of treating female urinary incontinence.

15 While all of the aforementioned prior art constructions are more than adequate for the basic purpose and function for which they have been specifically designed, they are uniformly deficient with respect to their failure to provide a simple, efficient, and practical method and apparatus for installing a urethral sling in a safe and simple manner with minimal trauma to the patient's body.

20 All of the recent surgical procedures that have been developed to install a polypropylene sling tape in an underslung relationship to a woman's urethra for controlling incontinence require that an incision be made in the vaginal and abdominal

walls which result in what is now believed to be an unnecessary surgical trauma for the patient.

5 In addition, the majority of surgical instruments that are currently employed in this medical procedure employ one or more curved tubular instruments wherein, the pointed tip of the curved instrument must pass between the bladder and the symphysis which requires great care and skill on the part of the surgeon.

10 As a consequence of the foregoing situation, there has existed a longstanding need in the medical field for a new and improved method and apparatus for installing a sub-urethral tape sling in an underslung relationship in a woman's urinary tract; and, the provision of such a method and apparatus is the stated objective of the present invention.

BRIEF SUMMARY OF THE INVENTION

15 Briefly stated, the urethral sling introducer that forms the basis of the present invention comprises in general an actuator handle unit, an instrument unit and a tape gauge unit wherein, the actuator handle unit operatively deploys a first captive piston moveably disposed within the instrument unit to captively grasp one end of a urethral sling tape as the instrument unit passes sequentially through a pair of incisors in the patient's vaginal wall.

20 As will be explained in greater detail further on in the specification, the sling tape is further slidably disposed within the tape gauge unit which comprises a transparent sheath member bearing indicia that allows the surgeon to quickly and visually determine the exact length of the portion of the sling tape that has been inserted into the first incision in the vaginal wall.

25 The instrument unit comprises in general a hollow curved tubular member having a ported and conical tip wherein, the interior passageway of the curved tubular member is dimensioned to receive a piston element mounted on one end of an elongated spring element the other end of which is attached to a second locking piston operatively associated with the handle unit.

30 In addition, the handle unit comprises a hollow handle member dimensioned to slidably receive the locking piston which has a fluid passageway that allows fluid introduced through a tubular connector element to pass through the locking piston and the curved tubular member through the capture piston and then through the ports and

aperture in the conical tip to facilitate the passage of the tip between the bladder and the symphysis.

5 In addition, the locking piston is designed to cooperate with the handle unit such that in a first position the locking piston causes the capture piston to be retracted below a capture aperture formed in the curved tubular member; and, in a second position the captive piston will captively engage one end of the polypropylene sling tape that has been previously inserted into the capture aperture.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

10 These and other attributes of the invention will become more clear upon a thorough study of the following description of the best mode for carrying out the invention, particularly when reviewed in conjunction with the drawings, wherein:

FIG. 1 shows the urethral sling introducer that forms the basis of this invention in use;

FIG. 2 is a front elevation view of the urethral sling introducer;

15 FIG. 3 is a cross-sectional view taken through line 3-3 of Fig. 2 and rotated 90°;

FIG. 4 is an enlarged front detail view of the upper portion of the instrument unit;

20 FIG. 5 is an enlarged side detail view of the upper portion of the instrument unit;

FIG. 6 is an enlarged front detail view showing the sling tape threaded through the capture aperture;

FIG. 7 is an enlarged side detail view showing the sling tape captively engaged in the capture aperture via the capture piston;

25 FIG. 8 is an external view of the locking piston;

FIG. 9 is a cross-sectional view of the locking piston; and,

FIG. 10 is a series of sequential views illustrating the operation of the tape gauge unit.

DETAILED DESCRIPTION OF THE INVENTION

As can be seen by reference to the drawings, and in particular to FIG. 1, the urethral sling introducer that forms the basis of the present invention is designated generally by the reference number **10**. The sling introducer **10** comprises in general an instrument unit **11** and a handle unit **12** that are used to operatively engage and release a polypropylene sub-urethral sling tape **100** during surgery wherein, as part of the surgical procedure, a tape gauge unit **13** is also employed to assist the surgeon in inserting equal amounts of tape through two vaginal incisions. These units will now be described in seriatim fashion.

As shown in Figs. 2 through 5, the instrument unit **11** comprises a curved elongated hollow tubular member **20** the upper end of which is provided with a contoured capture aperture **21** and terminates in a hollow conical tip **22** provided with a plurality of fluid outlet ports **23** wherein, the purpose and function of the capture aperture **21** and the fluid outlet ports **23** will be described in greater detail further on in the specification.

Still referring to Figs. 2 through 5, it can be seen that the interior of the elongated hollow tubular member **20** is dimensioned to slidably receive a hollow capture piston **24** the upper end of which is chamfered and the lower end of which is attached to one end of an elongated spring element **25** that extends both through the instrument unit **11** and a portion of the handle unit for reasons that will be explained presently.

As can best be appreciated by reference to Figs. 2 and 3, the handle unit **12** comprises an elongated hollow handle member **30** the upper and lower portions of which are provided with enlarged gripping surfaces **31 32** wherein, the upper end of the handle member **30** is fixedly secured to the lower end of the curved hollow tubular member **20** and the lower end of which defines an enlarged fluid chamber **33** dimensioned to slidably receive a locking piston **40**. In addition, the lower end of the handle member **30** is adapted to receive a threaded cap element **34** to move the locking piston **40** upwardly and downwardly within the enlarged chamber **33** in the handle member **30**.

Turning now to Figs. 3, 8, and 9, it can be seen that the elongated locking piston **40** is provided with a stepped shoulder axial bore **41** and a transverse fluid port

42 disposed adjacent to but spaced from the distal end of the axial bore **41** which fixedly receives the lower end of the elongated spring element **25**.

In addition, the exterior surface of the locking piston **40** is provided with an outwardly projecting collar **43** which is flanked by a pair of peripheral grooves **44 45** wherein, the collar **43** acts as a stop to limit the intrusion of the locking spool **40** into the enlarged chamber **33** of the handle member **30** and one of the grooves **45** is dimensioned to receive an O-ring **46** that is sealingly engaged with the interior walls of the enlarged chamber **33** while the other groove **44** is dimensioned to receive another O-ring **47** that will prevent the cap element from becoming disengaged with the lower end of the locking piston **40**.

Furthermore, as shown in Fig. 2, the lower end of the locking piston **40** is further provided with a tube connector **48** that is adapted to receive a saline supply line such that a supply of saline fluid can be delivered through the handle unit **12** and the instrument unit **11** during the surgical procedure.

As can best be seen by reference to Figs. 6 and 7, the contoured capture aperture **21** has an enlarged upper portion **21'** and an elongated narrow lower portion **21''** wherein, the lower portion **21''** is dimensioned to receive the lower portion of the sling tape **100** in its uncompressed state, while the enlarged upper portion **21'** of the capture aperture **21** allows the compressed bulk of the end of the sling tape **100** to be released without catching on the capture aperture **21** when the capture piston **24** is withdrawn within the hollow tubular member **20** when the conical tip **22** reaches a desired location beneath the patient's abdominal wall.

The method of use of the sling introducer **10** proceeds once a surgeon has made a pair of incisions in the vaginal wall of the patient on opposite sides of the urethral opening. Once these incisions have been made, the surgeon will back off the cap element **34** to allow the locking piston **40** to be partially withdrawn from the chamber **33** in the handle member **30**.

This action causes the capture piston **24** to be withdrawn from a blocking position relative to the capture aperture **21** which can then receive one end of the sling tape **100**. At this point, the capture piston is re-inserted into the chamber **33** so that the spring element **25** will force the capture piston **24** into gripping engagement with

the sling tape **100** which is gripped between the bottom of the conical tip **22** and the top of the capture piston **24** whereupon the cap element **34** is advanced upwardly relative to the bottom of the handle member **30**.

5 Once the sling tape **100** is grasped by the sling introducer **10**, the surgeon will insert the conical tip **22** of the instrument unit **11** into one of the vaginal incisions using the saline solution to facilitate the passage of the conical tip between the bladder and the symphysis until such time as the presence of the conical tip **22** can be felt beneath the patient's abdominal wall.

10 At this juncture, the inserted end of the sling tape **100** is released by withdrawing the capture piston **24** from engagement with the sling tape and the instrument unit **11** is withdrawn from the first incision. Then in order for the surgeon to insure that equal lengths of the sling tape **100** are inserted into the pair of vaginal incisions, the tape guide unit **13** comes into play.

15 In accordance with the teachings of this invention and as depicted in Fig. 10, the tape guide unit **13** comprises a transparent sheath member **50** that is slightly longer than, and slidably disposed on, the sling tape **100** wherein, the exterior surface of the sheath member is provided with different colored ascending/descending numerical indicia **51**.

20 In use the sheath member **50** is snugged against the captive end of the sling tape **100** as the sling tape **100** is inserted through the first vaginal incision by the instrument unit **11**. Then once the sling tape **100** is positioned against the abdominal wall and released, the sheath member **50** is withdrawn until the top of the sheath member **50** is visible outside of the vaginal incision. At this point, the surgeon will note the position of the free end of the sling tape relative to one set of colored indicia and then sever both the sling tape **100** and the sheath **50** at the same numerical value
25 on the different colored indicia.

30 In this manner, the uncut free end of the sling tape **100** can be captively engaged by the sling introducer **10** as previously described and inserted into the other vaginal incision to insure that equal lengths of sling tape **100** are installed without the necessity of creating abdominal incisions to trim the tape ends.

Although only an exemplary embodiment of the invention has been described in detail above, those skilled in the art will readily appreciate that many modifications

are possible without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the following claims.

5 Having thereby described the subject matter of the present invention, it should be apparent that many substitutions, modifications, and variations of the invention are possible in light of the above teachings. It is therefore to be understood that the invention as taught and described herein is only to be limited to the extent of the breadth and scope of the appended claims.